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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,570	02/06/2002	Vitaly Vodyanoy	35721/243744 (5721-18)	6923

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EXAMINER	
CHEU, CHANGHWA J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/068,570	VODYANOY ET AL.	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-19 and 23-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 6-19* is/are rejected.

7)☒ Claim(s) *3-5 and 23-25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on 6/6/2005 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 2, 20-22 are cancelled.
2. Claims 1, 3-19, 23-25 are under examination.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claims 1, 8-9 are rejected under 35 U.S.C. 102(e) as being anticipated over Wagner et al. (US 6630358)

Wagner et al. teach a protein array for in vitro screening of biomolecular activity. Wagner et al. teach immobilizing a plurality of peptides of interest on the organic thinfilm, such as Langmuir-Blodgett film, of a sensor substrate (Col. 7, line 18-28; Abstract). Wagner et al. also disclose various means for detection, including fluorescence correlation

spectroscopy (FCS), infrared range, optical waveguides, fluorescence resonance energy transfer (FRET) (Col. 26, 17-25). The detection methods can be used to both quantitative and qualitative determination of the interest of peptides and inherently include measurement of the signals due to the exposing of the peptides to the sensor (Col. 26, line 17-20).

With respect to claim 8-9, Wagner et al. teach using biotin-streptavidin system to increase specificity and selectivity for the target molecules in the protein array assay (Col. 24, line 17-25).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. in view of Ebato et al. (Anal. Chem. 1994 Vol. 66: 1683).

Wagner et al. reference has been discussed but is silent in using of spacer for coupling the peptides of interest.

Ebato et al. disclose that using a spacer in the Langmuir-Blodgett film can increase coupling of the target molecules (See Abstract; Figure 1 and 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Wagner et al. with the spacer technique as taught by Ebato et al. in order to increase the sensitivity of the assay.

5. Claims 10-13, 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. in view of Samoylova et al. (Muscle & Nerve 1999 April, page 460).

Wagner et al. reference has been discussed but does not explicitly teach in vivo screening of potential ligands.

Samoylova et al. disclose a muscle-specific peptide of interest, such as ASSLNIA, can enhance in vivo skeletal and cardiac muscle binding (See Abstract and Method). Samoylova et al. teach using phage library encoding the peptides of interest for *in vivo* screening candidate ligands in mice model (See Figure 3 and Abstract). The phage selected process includes several rounds of passing phage expressing peptides (See page 462, third paragraph in Results, and Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have motivated Wagner et al. to incorporate peptide of interest, for example, ASSLNIA, to the sensor surface to screen candidate muscle-specific binding ligands with reasonable expectation of success because it has been shown that ASSLNIA peptide is a muscle-specific peptides (e.g. target peptide) which can be used in the protein array by Wagner et al. for screening.

6. Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. in view of Hengerer et al. (Biosensor & Bioelectronics 1999 14: 139).

Wagner et al. reference has been discussed but is slient in using piezoelectric crystal or acoustic wave sensor as the detection means.

Hengerer et al. disclose an immunosensing system based on a quartz crystal bicrobalance (QCM), such as acoustic sensors on piezoelectric crystals vibration to detect target molecules in a sample (See Abstract). Hengerer et al. teach coupling (e.g. immobilized) the peptides of interest on the surface of the sensor and quantifying the signals output from the sensors for detecting corresponding ligands (page 140, second paragraph; Figures 1-6). Therefore, it would have been obvious to one ordinary skilled in the art at the time the invention was made to have provided Wagner et al. the alternative means for detection such as piezoelectric crystal or acoustic wave sensor as taught by Hengerer et al. since analogous field is involved, e.g. measuring peptides immobilizing on a substrate, and alternative means of measurement merely requires routine practice in the art.

Response to Applicant's Arguments

7. The rejections of claims 1, 8-9 under 35 U.S.C. 102(e) as being anticipated over Wagner et al. are maintained.

Applicant argues that (1), the Wagner et al. is an "in vitro" screening method; (2) Wagner et al. is silent in "using piezoelectric crystal or acoustic wave sensor as detection means; (3) the recited clause (d) and (f), "signal output" features can distinguish from Wagner et al. reference.

Applicant's arguments have been considered but are not persuasive. First of all, there is no recitation of "in vivo" in claim 1 language. Applicant also recites "in vitro" in claim 18 indicating the instant method is performed under "in vitro' condition.

Second, no language of using piezoelectric crystal or acoustic wave sensor is recited in the claims 1, 8-9. Hence, this is not a material issue needed to addressed.

Third, the "signal output" is a general term indicating any signal corresponding to the binding event, not necessary limited to the piezoelectric crystal or acoustic wave sensor. Therefore, the 102(e) rejection is deemed proper.

8. The rejections of claims 6-7 under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. in view of Ebato et al. are maintained.

Applicant argues that Ebato reference does not teach the use of a peptide coupled to a sensor, and the combination of Wagner and Ebato et al. merely suggests that one could experiment on combining various aspects of the teachings in order to test new devices and methods for performing various assays. Therefore, this does not constitute a proper showing of obviousness under Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987) (stating that "the obvious-to-try' situation exists when a general disclosure may pique the scientist's curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claimed result would be obtained if certain directions were pursued").

Applicant's arguments have been considered but are not persuasive. First of all, Ebato et al. reference is not to show the feature of use of a peptides coupled to the sensor which has been shown in the Wagner et al. reference. Ebato et al. reference is for providing the teachings of use of a spacer to increase the coupling efficiency of the peptides (See above). It is not "obvious-to-try", rather the suggestion and motivation is provided to increase coupling efficiency by use of the spacer.

9. The rejections of claims 10-13, 16-19 under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. in view of Samoylova et al. are maintained.

Applicant argues that the feature of "signal output" from claim 1, clause (d) and (f) can distinguish from Wagner et al. reference, and there is lack of suggestion or motivation to combine the Samoylova et al. reference.

Applicant's arguments have been considered but are not persuasive. As discussed before, the "signal output" is a general term for any signal detection, not limited to certain biosensors. Furthermore, Wagner et al. teach screening of potential peptides, proteins by the array sensors. The instant claim language does not recites any specific peptides, e.g. SEQ ID No.. Therefore, the teachings of Samoylova et al. can be a suggestion or motivation to Wagner et al. because Samoylova provides the necessary methods of preparing peptides of interests, e.g. bacteriophage library containing target peptides and expressing in cell system. One ordinary skill in the art would have used Samoylova et al. method to produce peptides of interest since it is well-known and routinely practiced in the art by using the phage library to select peptides.

10. The rejections of claims 14-15 under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. in view of Hengerer et al. are maintained.

Applicant argues that Wagner et al. do not teach use of a piezoelectric crystals, and Hengerer et al. do not teach use of Langmuir-Blogdett film to couple peptides, so that there is lack of suggestion or motivation to combine the two references for prima facie rejection under 35 USC 103 (a).

Applicant's arguments have been considered but are not persuasive. With respect to the different feature, Wagner et al. teach use of Langmuir-Blogdett film to couple peptides but is silent of use piezoelectric crystal as a detection means. The reference of Hengerer et al. provides the piezoelectric crystal as the detection means, and Hengerer et al.

reference is also in an analogous art, e.g. teaching coupling peptides on the surface of biosensor and quantifying the output signals corresponding to the presence of the ligand (page 140, second paragraph; Figure 1-6). Thus, there is suggestion and motivation to provide Wagner et al. piezoelectric crystal means for detection, and this merely requires routine practice in the art.

Allowable Subject Matter

11. Claims 3-5, 23-25 would be allowable if rewritten to include all of the limitations of the base claim and any intervening claims.

12. The following is a statement of reasons for the indication of allowable subject matter: no prior art teaches or fairly suggests preparing a Langmuir-Blogett film for immobilizing peptide of interest with specific features as recited in claim 3, including comprising at least one phospholipid containing no more than 25% of a volatile organic solvent, immersing into an aqueous subphase at about 90-170 degrees to an air/liquid interface where the subphase comprising at least one monovalent cation and at least one bivalent cation, and delivering at a rate of about 0.02-4.0 ml per minute for form a monolayer and compressing with an optimal surface pressure.

Conclusion

13. No claim is allowed.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu
Examiner
Art Unit 1641

August 3, 2005

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08/05/05